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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,147	05/08/2001	Scott E. Andersen	16517.251 [38-21(51914)B]	1268

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EXAMINER	
CLOW, LORI A	
ART UNIT	PAPER NUMBER
1631	11

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/850,147	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- *The MAILING DATE of this communication appears on the c ver sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 12-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, and 12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' arguments, filed 11 April 2003, have been fully considered and are not deemed persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 2, and 12-17 are currently pending. Claims 3-11 have been cancelled.

Claims Rejections-35 USC 101

For reasons set forth in the previous Office Action and reiterated below, the rejection under 35 USC 101 is maintained.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"**Specific**" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"**Substantial**" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"**Credible**" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's

assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1, 2, and 12-17 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

The claimed nucleic acids are not supported by a specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any nucleic acid. The specification states that the nucleic acid compounds may be useful as markers, the isolation of polypeptides, hybridization probes, primers, the isolation of full-length cDNAs or genes, which would be used to make protein and optionally further usage for mapping and numerous other generic genetic engineering usages, such as antisense production. In fact, the specification summarized modern biotechnology generally but never connects any of the specifically elected sequences to any particular or specific utility. This wishlist desire for a utility for the claimed sequences falls short of a readily available utility. These are non-specific uses that are applicable to nucleic acid(s) and/or proteins in general and not particular or specific

to the nucleic acid being claimed. Furthermore, no disclosure of the actual protein that is encoded by Seq ID No. 1 is given. No established percent homology to a known sequence specific to Seq ID No. 1 is disclosed. Finally, there is no disclosure of an open reading frame or a proposed encoded protein pertaining to Seq ID No. 1.

Further, the claimed nucleic acids are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting research to functionally characterize the protein. The need for such research clearly indicates that the protein and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the proteins that are to be produced as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context or use. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleic acid and/or

protein compound(s) such that another non-asserted utility would be well established for the compounds.

It is noted that applicant has identified stated sequence similarity to the claimed sequences. However, no specific homologies are mentioned for instant Seq ID No. 1. Absent factual evidence, one skilled in the art would have reason to doubt that proposed sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence. Furthermore, it is unclear whether the similar sequences identified in the prior art have actually been tested for the biological activity or whether this also is an asserted biological activity based upon sequence similarity to yet a different sequence. Note that it would have been well known in the art that sequence similarity does not reliably correlate to structural similarity and that structural similarity does not reliably result in similar or identical biological activities. For example, it would have been well known that even a single nucleotide or amino acid change or mutation could destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. Several publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research. See Attwood (Science, 290:471-473, 2000); Gerhold et al. (BioEssays, 18(12):973-981, 1996); Wells

et al. (Journal of Leukocyte Biology, 61(5):545-550, 1997); and Russell et al. (Journal of Molecular Biology, 244:332-350, 1994). However, this level of factual evidence is absent here.

Applicant asserts that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown (*Raytheon Co. v. Roper Corp.* (page 5, second paragraph)). Applicant argues that the examiner asserts and the specification describes a utility by reciting "a nucleic acid may be utilized to obtain a protein". However what *specific* utility is described by Seq ID NO. 1? SEQ ID NO. 1 only fits into a *general* utility that would be applicable to the broad class of the invention, which is to isolate a protein. What protein? No disclosure of the actual protein that is encoded by Seq ID No. 1 is given. Under the new Utility Examination Guidelines, as clearly indicated above, a patent application must show that the proposed gene's utility is "specific, substantial **and** credible" and that the there must be "well-established utility". Accordingly, applicant has not shown a particular biological reaction involving the protein product of SEQ ID NO. 1, for instance. Nor has applicant shown known homology of SEQ ID NO. 1 to a gene of another species. The specification fails to indicate any known entity of SEQ ID NO. 1, including the function of the said protein encoded by SEQ ID NO.1, the tissue distribution of the protein, or any known physiological characteristic of SEQ ID NO. 1.

Applicant cites several decisions including *Raytheon Co v. Roper Corp.*724F.2d 951, 958, 220 USPQ 592 598 (Fed Cir 1983); and *Carl Zeiss Stiftung v. Reinshaw PLC*, 945 F2d 1173, 1180, 20 USPQ .2d 1094 1100 (Fed Cir 1991) in support of their assertion that the Guidelines contravene prevailing law, however, these decisions are distinguishable from this

application on their facts, and Applicant is reminded of *Brenner v. Manson* (supra) which stated that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As set forth above, the myriad of asserted utilities are general utilities applicable to a broad class of compounds, and do not meet the specific, substantial and credible criteria for utility under the present guidelines. The additional potential utilities suggested by Applicant (identifying and generating mutations, investigating links, identifying and isolating related molecules etc.) are an invitation to do further research to search for a specific and substantial utility for each polynucleotide claimed and/or disclosed. No particular activity, function, or disease link is ascribed to any particular claimed polynucleotide. Further, no readily apparent well-established utility for any one polynucleotide is set forth in the specification.

Applicant further argues that under the published Utility Examination Guidelines, certain other types of inventions would not be patentable, such as microscopes and golf clubs, however, the utility of those apparati are not sufficiently related to the isolated polynucleotides under examination such that any definite conclusions as to utility can be drawn. Applicant notes that "An important utility of a microscope resides in its use to identify..." however, whether that utility is the only utility or the only patentable utility of those inventions is not clear, and not at issue here. For example, a microscope is NOT analogous to a nucleic acid sequence. It is clear that a microscope has a particular function in that it contains SPECIFIC mechanisms, working in concert, that enable it function. For instance, a confocal microscope has a well-defined structure, containing a light source having excitation wavelengths appropriate for particular sample fluorescent dyes, a scanner to scan the light, an objective lens to condense the light, a detector to

detect fluorescence, a confocal pinhole, etc... However, SEQ ID NO. 1 has no defined SPECIFIC function that allows one to identify a specific protein product, as is stated in the claims. As is acknowledged by applicant on page 6, 3rd paragraph, the claimed nucleic acid molecule encompasses many utilities, however, none are specifically defined as they relate specifically to SEQ ID NO. 1.

It is acknowledged that applicant has provided copies of references in support of arguments for similarity analysis in functional prediction. However, the fact remains that the specification provides no insight into the similarity of SEQ ID NO. 1 with any other known sequence. Instead it provides a blanket statement that this technology could be used, without actually providing evidence that it has been used for the SPECIFIC SEQ ID NO. 1.

Claims Rejections-35 USC 112

The rejections under 35 USC 112, 1st paragraph are maintained for the reasons set forth in the previous Office Action and reiterated below.

Applicant is directed to the published Written Description Examination Guidelines, published in the Federal Register, Vol.66, No. 4, pages 1099-1111, 01/05/01.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 12-17 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or, alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 1 which corresponds in some undefined way to cDNA/genomic DNA encoding plant species of protein/nucleic acid. SEQ ID NO: 1 per se meets the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 1 and 2 are directed to encompass fragments and gene sequences comprising SEQ ID NO: 1, corresponding sequences from other species, mutated fragment sequences, allelic variants, splice variants, and so forth. None of these additional sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. This is a rejection based on a lack of WRITTEN DESCRIPTION.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Furthermore, no disclosure of an open reading frame or encoded protein of Seq ID No. 1 is given, thereby causing serious questions regarding the description of the instant Seq ID. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 1, but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant argues that these amendments obviate the rejection under 35 USC 112, written description. These amendments and arguments are not persuasive. The specification only discloses the particular elected cDNA EST sequences, which also inherently discloses the full length exact complement of each sequence. However, the specification does not disclose the full genomic information of the gene from which the EST was cloned. Use of the term "comprising" reads on intact genomic material comprising enhancers, promoters, introns, and splice sites, etc. No open reading frames are identified in any elected sequence such that one of skill in the art would be able to determine where such features could be within the sequence. Limiting the claims to a "purified polynucleotide consisting of the cDNA selected from the group consisting of X, Y and Z" could overcome this rejection.

Written description of an invention requires "a precise definition, such as by structure, formula, chemical name, or physical properties." *Eli Lilly*, 119 F.3d at 1566, 43 USPQ2d at 1404. The specification does not set forth any of these definitions for other polynucleotides which fall within the scope of the claims. An applicant may also show written description of an invention by combining a partial structure, physical properties, or chemical characteristics with a known or disclosed specific function. However, no specific function or activity had been ascribed to any one elected sequence in the specification, as filed.

The written description requirement for any claim drawn to a genus can be met through sufficient description of a representative number of species within the genus. The broadest claim for each elected polynucleotide is a separate genus. The specification, as filed, only discloses the single species of each genus, which is not sufficient to support the assertion that Applicant was in possession of the entire genus being claimed.

Therefore, claims drawn to purified polynucleotides consisting of the cDNA selected from the group consisting of X, Y and Z, but not the full breadth of the claims, would meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
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June 23, 2003

Lori A. Clow, Ph.D.
Art Unit 1631